

MAR 26 2002

K012406

APPENDIX 5

510(K) SUMMARY

FOR

**Interpore Cross International
ACCESS™ SEQUESTRATION SYSTEM**

510(k) SUMMARY

SUBMITTED BY

Prosie Rey-Fessler, RAC
Director, Quality Assurance and Regulatory Affairs
Interpore Cross International
181 Technology Drive
Irvine, California 92618

July 27, 2001

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Autotransfusion Apparatus
Common/Usual Name: Sequestration or Separation Device
Product Classification: Class II
Proprietary Name: Access™ Sequestration System

PREDICATE DEVICE

The predicate device is the Dideco Compact-A and Compact-M Autotransfusion Systems which was cleared under 510(k) K963759.

INDICATIONS-FOR-USE

The Interpore Cross International Access™ Sequestration System is intended to separate and collect an autologous plasma fraction rich in platelets and white cells from the patient's whole blood perioperative to a surgical procedure.

DEVICE DESCRIPTION

The Access™ Sequestration System is comprised of two major components:

- a) **Reusable separation apparatus:** The Access sequestration machine is an electromechanical microprocessor-controlled device contained in an enclosure which incorporates the following system components: the user display and function keys, centrifuge rotor, centrifuge chamber housing, peristaltic pump, red blood cell sensors, bubble sensor, pinch valves, and the power supply unit. In addition, the system includes the electronic components and system software which controls and monitors the blood processing procedure.
- b) **Single Use Processing Disposable set:** The Access Sequestration Disposable Set consists of the separation chamber, two holding bags, and the associated tubing, clamps, connectors and protective caps.

COMPARISON TO THE PREDICATE DEVICE

The AccessTM Sequestration System is substantially equivalent to Dideco Compact-A and Compact-M Autotransfusion Systems that is currently manufactured and distributed by Sorin Biomedical Inc.. Based on the same intended use, technological characteristics and comparative performance, Interpore Cross International believes that sufficient evidence exists to reasonably conclude that this device is substantially equivalent to the existing legally marketed device.

SUMMARY OF TESTING

Based on the performance testing conducted, the proposed device has been demonstrated to be substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 2002

Mr. Prosie Rey-Fessler, RAC
Director, Quality Assurance and Regulatory Affairs
Interpore Cross International
181 Technology Drive
Irvine, CA 92618-2402

Re: K012406
Trade Name: Access™ Sequestration System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (two)
Product Code: CAC
Dated: March 8, 2002
Received: March 11, 2002

Dear Mr. Fessler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

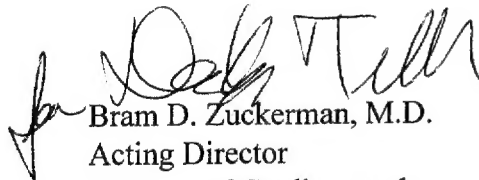
Page 2 - Mr. Prosie Rey-Fessler, RAC

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: AccessTM Sequestration System

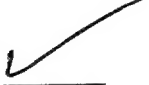
Indications-For-Use:

The Interpore Cross International AccessTM Sequestration System is intended to separate and collect an autologous plasma fraction rich in platelets and white cells, from the patient's whole blood perioperative to a surgical procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number 206406

Prescription Use 
(PER 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)